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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,900	02/24/2004	Eugene R. Cooper	029318-1003	1015

31049 7590 01/26/2007

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

TT

Office Action Summary	Application No.	Applicant(s)	
	10/784,900	COOPER ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-73 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-73 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date all.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-26 and 31-73 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-34 of U.S. Patent No. 6,908,626 ('626) in view of Meyer et al. USPN 6,221,377 ('377). The '626 patent claimed a formulation comprising: nanoparticulate of active agent having an effective average particle size of less than about 1 micron; and (b) at least one surface stabilizer adsorbed onto the surface of the nanoparticulate active agent particles wherein the concentration of the surface stabilizer is from about 0.5% to about 99.999%(w/w), based upon the total weight of the nanoparticulate active agent and the surface stabilizer, and wherein the surface stabilizer is selected from the group consisting of a nonionic surface

stabilizer, an anionic surface stabilizer, a cationic surface stabilizer, and an ionic surface stabilize. Average particle size in nanometer is found in claim 2. Active agent is found in claim 19. Surface stabilizer is found in claims 20-22. Dosage formulations are found in claims 11-17. Method of making the formulation is found in claim 25. Method of treating a mammal is found in claim 34. The '626 patent does not expressly disclose meloxicam as an active agent.

Meyer teaches analgesic agent includes meloxicam (column 6, lines 18-67; and claim 47). Thus, it would have been obvious to one of ordinary skill in the art to modify the formulation of the '626 patent to include meloxicam as an active agent, because Meyer teaches meloxicam is a well known analgesic agent, because the '626 patent teaches a formulation suitable for a wide variety of active agents including analgesic.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-17, 63 and 64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claims are rejected because they do not identify the structure, material, or acts set forth in the specification that

would be capable of carrying out the functional properties recited in the claims. It appears that the specification does not provide adequate teaching and/or support as to how the composition can result in the claimed release profile, and the claimed C_{max}. Accordingly, the structure which makes up the formulation must be clearly and positively specified.

Claims 14-17, 63 and 64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims lack the description of the possible genus with the recited functional characteristics.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 42, 62 and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13, 42 and 62 contain the trademark/trade name "MIRAPOL™" or "ALKAQUAT™". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade

name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name.

Claim 73 is rejected to for being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claims. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-17, 26-42, 50-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liversidge et al. WO 93/25190, in view of Meyer et al. US 6,221,377.

Liversidge teaches a dispersible nanoparticle having an effective average particle size of less than about 400 nm, the nanoparticle comprising NSAID and surface modifier (abstract; and page 2, lines 21-25). NSAID is present in crystalline phase, and in an amount 0.1%-60% (page 3, lines 31-35; and page 7, lines 31-33). Liversidge further teaches a pharmaceutical formulation for the treatment of a mammal, the formulation comprising the dispersible nanoparticle, and an acceptable carrier (page 2, lines 26-28). Liversidge also teaches a process for preparing the nanoparticle

comprising the steps of dispersing an NSAID in a liquid dispersion medium; wet grinding the NSAID in the presence of grinding media, wherein the pH of said medium is within the range of 2-6; and adding surface modifier in an amount of 0.1-90% (page 7, lines 20 through column 8, lines 1-17; and pages 9-10). The claimed surface modifier is disclosed in pages 5-6. Two or more surface modifiers can be used in combination (ID). The pharmaceutical formulation can be processed into dosage form such as solid, liquid for administration by parenteral, oral, rectal, and the like (page 11, lines 29-36).

Liversidge does not explicitly teach the claimed meloxicam.

Meyer teaches dosage form comprising analgesic or NSAID includes oxicams such as meloxicam, piroxicam and isoxicam (column 6, lines 38-42). Thus, it would have been obvious to one of ordinary skill in the art to modify the formulation of Liversidge using meloxicam in view of the teaching of Meyer, because Meyer teaches the equivalency of meloxicam, piroxicam, and isoxicam, and because Liversidge teaches a formulation suitable for drugs including oxicams.

It is noted that Liversidge does not expressly teach the claimed release profile, and the claimed C_{max}. However, absent of evidence to the contrary, the burden is shifted to applicant to show that the formulation taught by Liversidge does not have the claimed release profile. This is because Liversidge teaches a nanoparticle formulation using the claimed surface modifier, carrier, and parameters.

Claims 1-17, 26-42, 50-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ryde et al. US 6,375,986, in view of Meyer et al. US 6,221,377.

Ryde teaches a solid dosage form comprising nanoparticulate composition comprising poorly water soluble active agent, at least one polymeric surface stabilizer, and (DOSS) (see abstract, column 6, lines 53-67). The nano-particle having diameter less than 1 μm (column 6, lines 24-34), wherein at least 90% of the nano-particle population having diameter of less than 200 nm (column 7, lines 63 through column 8, lines 1-5). The surface stabilizers is disclosed in column 7, lines 33-53, which can be used in a concentration from 0.01 to about 90% (column 9, lines 18-22). The active agent is used in a concentration of about 99.8 to about 0.1% (column 9, lines 24-28). The nano-particle can be made by method selected from milling, precipitation, drying dispersion, high shear granulation, fluid bed granulation, and spray coating (column 9, lines 38 through column 10, lines 1-41). The dosage form can be administered rectally, intravaginally, or orally in the form of tablet, powder, capsule, pills, and granule (column 10 ,lines 45-67).

Ryde does not explicitly teach the claimed meloxicam.

Meyer teaches dosage form comprising analgesic or NSAID includes oxicams such as meloxicam, piroxicam and isoxicam (column 6, lines 38-42). Thus, it would have been obvious to one of ordinary skill in the art to modify the formulation taught by Ryde using meloxicam in view of the teaching of Meyer, because Meyer teaches analgesic agents including meloxicam, and because Ryde teaches a formulation suitable for a variety of drugs including analgesic (claim 14).

It is noted that Ryde does not expressly teach the claimed release profile, and the claimed C_{max}. However, absent of evidence to the contrary, the burden is shifted to applicant to show that the formulation taught by Ryde does not have the claimed release profile. This is because Ryde teaches a nanoparticle formulation using the claimed surface modifier, carrier, and parameters.

Claims 18-25, 43-49 and 68-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liversidge et al. or Ryde et al. US 6,375,986, in view of Desai et al. WO 01/45706 A1 or Courteille et al. US 5,384,124.

Liversidge and Ryde are relied upon for the reasons stated above. The cited references do not teach the second particle population.

Desai teaches a dual-release composition of low water soluble drug (COX-2 inhibitor) comprising first fraction of the drug in nano-particulate form having average diameter of about 200 to about 400 nm and a D90 particle size less then about 5 μm (page 18); and a second fraction of the drug in micro-particulate form having D10 particle size of between 25 to about 100 μm (page 20, 1st paragraph). The first fraction nano-particle drug can be present alone or in combination with one or more excipient, such as nano-particles of the drug have a surface modifying agent (PEG-400) adsorbed on the surface thereof (page 18, 3rd through page 19). The weight ratio of the first to the second fraction of the drug in the composition is about 1:10 to about 10:1 (page 22, 3rd paragraph). The composition can be in an oral dosage form including tablet, pills, hard

or soft capsule, lozenges, cachets, dispensable powder, granule, suspension or elixir (pages 37-38).

Courteille teaches a solid unitary composition comprising combination of nano-particle having diameter of less than 1 μm and micro-particle having diameter of between 1 μm to 2 mm (see abstract, column 2, lines 32-46). The mixture of nano/micro-particle contains one or more active agents of the same or different type (column 1, lines 66-68, and column 2, lines 23-31). The active agent can be selected from antibiotic, analgesic, tranquilizer, vitamins, and therapeutic agents for diseases of allergies, hormones, or gastrointestinal tract (column 5, lines 46-66). The mixture of nano/micro-particle is prepared by any known method (air-fluidized bed coating, turbine coating, simple extrusion, or micro-encapsulation) employing the use of a polymer or a macromolecular substance (surface stabilizer) selected from the group of cellulose derivatives, starch, polyamide, collagen, dextrin, gelatin, polyvinyl chloride or the like (column 2, lines 46-55, and column 3, lines 18-40). The mixture further comprises stabilizing agent, surfactant, and biding agent (column 4, lines 20 through column 5, lines 1-28). Courteille further teaches the solid dosage form comprises immediate release with a secondary controlled release of mixture of nano/micro-particle (column 6, lines 16-50). The solid dosage form is to be incorporated into pharmaceutical oral dosage form (column 6, lines 51-56).

Thus, it would have been obvious to one of ordinary skill in the art to modify the composition of Liversidge or Ryde to include the second particle population in view of the teachings of Desai or Courteille, because Desai and Courteille teaches

compositions suitable for analgesic drugs including COX inhibitor, and because Liversidge and Ryde teach the desirability of obtaining composition suitable for NSAID active agents.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit 1615

SUSAN TRAN
PRIMARY EXAMINER